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09/284,424 04/09/99 ALBRECHT

H 5500-01-TMC

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EXAMINER

MAIER, L

ART UNIT

PAPER NUMBER

1621

DATE MAILED:

10/25/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/284,424

Applicant(s)
Albrecht et al

Examiner
Leigh Maier

Group Art Unit
1621



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-43 is/are pending in the application.
- Of the above, claim(s) 9 is/are withdrawn from consideration.
- ☒ Claim(s) 32, 34, and 38-41 is/are allowed.
- ☒ Claim(s) 1, 2, 4-7, 10, 11, 16, and 18 is/are rejected.
- ☒ Claim(s) 3, 8, 12-15, 17, 19-31, 33, 35-37, 42, and 43 is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Claims 1-43 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, in part, and 10-43, in part, drawn to non-heterocyclic compounds, compositions, and methods of use.

Group II, claim(s) 9, 1-8, in part, and 10-43, in part, are drawn to heterocyclic compounds, compositions, and methods of use.

3. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The structural element linking the compounds of the genus is not structurally distinctive in view of the prior art. Dolle et al (1994) disclose N-benzyloxycarbonyl-L-valine-L-aspartic acid 2,6-dichlorobenzoyloxymethyl ketone as well as other

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compounds (see claim 2 for listing) in Group I. Dolle et al further disclose N-benzyloxycarbonyl-L-aspartic acid 2,6-dichloro-3-(2-N-morpholinylethoxy)phenoxymethyl ketone, as well as other compounds in Group II. Compounds in both groups are known; therefore, there is no special technical feature linking the two groups, and there can be no unity of invention.

4. During a telephone conversation with Mr. Charles Ashbrook on October 5, 1999, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8, in part, and 10-43, in part as they relate to non-heterocyclic compounds, compositions, and methods of use thereof. Upon request of the Examiner, Mr. Ashbrook also elected a single species, 3-[3-methyl-2-(phenethylcarbamoyl-methyl)-butyrylamino]-5-(naphthalen-1-yl-acetoxy)-4-oxo-pentanoic acid, as a starting point for the search. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9, in its entirety, 1-8, in part, and 10-43, in part, as they relate to heterocyclic compounds, compositions, and methods of use thereof are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Claims 1-8 and 10-43 are generic to both Groups and were examined to the extent that they read on the elected invention. Claim 9 is a species claim drawn to Group II. As such, it is withdrawn from consideration as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Dolle et al, Mjalli et al, Heng et al, Chapman et al, and Prasad et al.

a. Dolle et al (1994) disclose N-benzyloxycarbonyl-L-valine-L-aspartic acid 2,6-dichlorobenzoyloxymethyl ketone as well as other compounds (see claim 2 for listing) that anticipate this genus.

b. Mjalli et al (1994) disclose N-(1-oxo-3-phenylpropyl)-L-valyl-N-[1-(carboxymethyl)-2-oxo-3-(1-oxo-3-phenylpropoxy)propyl]-L-alaninamide (Table 1, entry 4c) which anticipates this genus.

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c. Heng et al disclose benzoic acid, 2,6-dichloro-, 4-carboxy-2-oxo-3-[[[5-[[[(phenylmethoxy)carbonyl]amino]-1-naphthalenyl]sulfonyl]amino]butyl ester (example 83) and other compounds (see table on p 11 for listing) that anticipate this genus.

d. Chapman et al disclose N-(N-phenylpropionyl-valinyl-alanyl)-3-amino-4-oxo-5-benzyloxy pentanoic acid as well as other compounds (see claim 17) which anticipate this genus.

e. Prasad et al disclose aspartate-based peptide α -[(2,6-benzoyl)oxy]methyl ketones in accordance with Formula I that anticipates this genus. See inhibitors 17 and 19 in Table 1.

10. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Dolle et al (1994). Dolle et al disclose 3-benzyloxycarbonylamino-5-[(2,6-dimethoxy)phenylcarbonyl]-4-oxo pentanoic acid as well as other compounds (see claim 2) with the R¹ structure that anticipates this claim.

11. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Dolle et al (1994). Dolle et al disclose 3-methoxycarbonylamino-5-[(2,6-dichloro)phenylcarbonyl]-4-oxo pentanoic acid as well as other compounds (see claim 2) with the R¹ structure that anticipates this claim.

12. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Dolle et al (1994). Dolle et al disclose 3-phenethylcarbonylamino-5-[(2,6-dichloro)phenylcarbonyl]-4-oxo pentanoic acid with the R¹ structure that anticipates this claim.

13. Claims 6, 7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Prasad et al. Prasad et al disclose aspartate-based peptide α -[(2,6-benzoyl)oxy]methyl ketones in

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accordance with Formula I with the R¹ structure that anticipates these claims. See inhibitors 17 and 19 in Table 1.

14. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Mjalli et al (1994). Mjalli et al disclose the compound mentioned in paragraph 9b above. This compound is in accordance with Formula I with the R² structure that anticipates this claim.

15. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Heng et al. Heng et al disclose the compound N-[(phenylmethoxy)carbonyl]-L-valyl-N-[1-(carboxymethyl)-3-[diphenylacetyl)oxy]-2-oxopropyl]-L-alaninamide (example 31) with the R² structure that anticipates this claim.

16. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Dolle et al (1994). Dolle et al disclose the compound mentioned in paragraph 10 above as well as others in accordance with Formula I having the R¹ and R² structures that anticipates this claim.

Allowable Subject Matter

17. Claims 32, 34, and 38-41 are allowed.

18. Claims 3, 8, 12-15, 17, 19, and 20-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and excluding any material drawn to the non-elected invention. Claims 31, 33, 35-37, 42, and 43 are objected to as containing material drawn to the

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non-elected invention. Claims 31, 33, 35-37, 42, and 43 would be allowed if rewritten to exclude material drawn to heterocyclic compounds.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can be reached on Monday through Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached at (703) 308-1701. The official fax number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

LCM

October 15, 1999

Rosalind Keys
ROSALYND KEYS
PATENT EXAMINER
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